NEWS RELEASE

Office of the Attorney General
Robert E. Cooper, Jr.

Department of Commerce and Insurance
Commissioner Leslie Newman

FOR IMMEDIATE RELEASE
Oct. 22, 2008
#08-42

CONTACT:
Sharon Curtis-Flair
(615) 741-5860

TN ATTORNEY GENERAL FILES JUDGMENT WITH PFIZER INC RESOLVING ALLEGATIONS OF DECEPTIVE MARKETING OF BEXTRA AND CELEBREX

Attorney General Bob Cooper and Consumer Affairs Director Mary Clement today announced Tennessee has filed a judgment with Pfizer Inc. resolving allegations regarding questionable marketing of Celebrex and Bextra.

Tennessee filed its stipulated judgment following a five-year investigation by 33 states into the company's promotion of the drugs designed to treat pain and inflammation. In addition to a $60 million payment to the participating states with Tennessee's share being $990,911, the order will largely restrict Pfizer's ability to deceptively promote all Pfizer products.

"This judgment, along with our other recent drug cases, should send a strong message to the pharmaceutical industry that we will not tolerate deceptive and misleading drug promotion," Attorney General Cooper said.

The multistate investigation was initiated in 2003 to determine whether Pfizer and another drug company Pharmacia, subsequently purchased by Pfizer, misrepresented that their jointly sold "Cox-2" drug Celebrex was safer and more effective than traditional non-steroidal antinflamatory drugs (NSAIDS) such as Ibuprofen (Advil) and naproxen (Aleve). As the investigation proceeded, additional concerns were raised regarding Pfizer's Cox-2 drug Bextra. Ultimately, the investigation concluded that Pfizer engaged in an aggressive, deceptive and unlawful campaign to promote Bextra "off label" for uses that had been expressly rejected by the Food and Drug Administration (FDA). While a physician is allowed to prescribe drugs for off-label uses, law prohibits pharmaceutical manufacturers from marketing their products for off-label uses.

Inexpensive, generically-available NSAIDS have been used for many years but have the potential to cause serious gastro intestinal (GI) side effects such as bleeding and perforations. Celebrex, Vioxx and Bextra were designed to reduce pain and inflammation without the negative

GI side effects of traditional NSAIDS. Although significantly more expensive than traditional NSAIDS, Cox-2 drugs have not been shown to be more effective relieving pain than traditional NSAIDS and neither Celebrex nor Bextra were ever proven to significantly reduce serious GI adverse events compared to traditional NSAIDS. Moreover, there are significant concerns that all three Cox-2 drugs increase the risk of serious cardiovascular adverse events such as heart attacks and strokes. Bextra also carries a risk of a serious and sometimes fatal skin condition. In 2004, due to safety concerns, Bextra and Vioxx were withdrawn from the market place and FDA required a "black box" safety warning for Celebrex.

In its complaint, the state alleges that despite the fact that significant safety concerns led FDA to reject a request to market high-dose Bextra for acute and surgical pain, Pfizer conducted a systematic, multi-pronged "off-label" promotional campaign for these very indications FDA denied. Among some of the allegations were that Pfizer:
*Distributed thousands of copies of a positive study from the denied application, as well as other positive studies relating to use of high dose Bextra, without distributing FDA's negative study or denied approval for acute and surgical pain.
*Co-opted influential doctors with paid consultancies and lavish weekends at high end resorts.
*Distributed thousands of samples of high-dose Bextra to specialties whose only possible use for high dose Bextra was off-label.
*Provided prizes and encouraged sales representatives to promote Bextra off label.
*Used supposedly non-promotional Continuing Medical Education to promote Bextra off-label.
*Misrepresented Bextra's safety.

Today's filed judgment is designed to address all concerns raised during the investigation regarding both Celebrex and Bextra. In addition, the judgment requires Pfizer to submit all television drug advertisements to the FDA for approval. If FDA does not respond within 45 days, Pfizer may run the advertisement but must still comply with any subsequent FDA comments regarding the advertisement and must notify the state that it is running the advertisement without FDA authorization. For any new drug for pain relief, Pfizer must delay direct-to-consumer advertising for up to 18 months should FDA recommend such a delay. Finally, the judgment generally prohibits Pfizer from deceptive and misleading advertising and promotion of any Pfizer drug, requires Pfizer to register all clinical trials, post clinical trial results, and ensure that subjects in Pfizer sponsored clinical trials give adequate informed consent.

The State's lawsuit and the judgment may be viewed by going online to www.tn.gov/attorneygeneral/

If consumers have complaints regarding prescription drug advertisements or any other deceptive conduct, they may go online to http://www.state.tn.us/consumer/ or call the Division of Consumer Affairs at (615) 741-4737 or toll-free in Tennessee at 1-800 342-8385.